K020446

510(k) SUMMARY

MAR 1 3 2002

Submitter's Name:	American Medical Systems, Inc.
Address:	10700 Bren Road West Minnetonka, MN 55343
Tel:	952-933-4666
Fax:	952-930-6157
Contact Person:	Elsa A. Linke
Date of Summary Preparation:	February 8, 2002
Device Common Name:	Bone Screw Inserter & Bone Screws
Device Trade Name:	Straight-In Bone Screw Fixation System
Device Classification Name:	Fastener, Fixation, Nondegradable, Soft Tissue Classification: Class II Product Code: MBI
Predicate Device:	Straight-In Bone Screw Fixation System K972622

Device Description

The Straight-In Bone Screw System consists of a motorized inserter and bone screws with attached suture. It is intended for soft tissue fixation to bones in the pelvic region (e.g., pubic, sacral, etc.) by means of bone screws threaded with suture. It is indicated for use during open or laparoscopic surgical procedures where soft tissue fixation to bones in the pelvic region is needed.

Indications for Use

The Straight-In Bone Screw System is intended for soft tissue fixation to bones in the pelvic region (e.g., pubic, sacral, etc.) by means of bone screws threaded with suture. It is indicated for use during open or laparoscopic surgical procedures where soft tissue fixation to bones in the pelvic region is needed (e.g., bladder neck suspension and urethral sling procedures for female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency).

Comparison to Predicate Device

The fundamental scientific technology of the device does not change with this modification. The only material change is the addition of braided suture to the device system.

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Supporting Information

The mechanical properties of the braided suture have been tested on the bench for compatibility with the Straight-In system. The suture complies with the USP Monograph for Non-Absorbable Sutures.

Conclusion

The proposed modification is equivalent to the predicate with respect to intended use, technological characteristics, and performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 3 2002

Elsa A. Linke
Regulatory Affairs Specialist
American Medical Systems, Inc.
10700 Bren Road West
Minnetonka, Minnesota 55343

Re: K020446
Trade/Device Name: Straight-In Bone Screw Fixation System
Regulation Number: 21 CFR §888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, MBI, GAT
Dated: February 8, 2002
Received: February 11, 2002

Dear Ms. Linke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

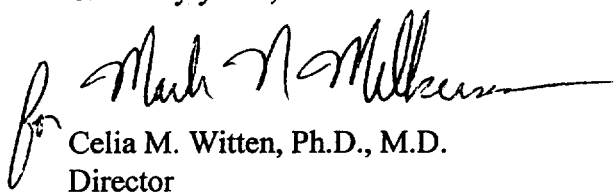
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE ENCLOSURE

510(k) Number: K020446

Device Name: Straight-In Bone Screw Fixation System

Indications for Use: The Straight-In Bone Screw System is intended for soft tissue fixation to bones in the pelvic region (e.g., pubic, sacral, etc.) by means of bone screws threaded with suture. It is indicated for use during open or laparoscopic surgical procedures where soft tissue fixation to bones in the pelvic region is needed (e.g., bladder neck suspension and urethral sling procedures for female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-off)
Division of General and Restorative Devices

510(k) Number _____

Prescription Use X
(Per 21 CFR801.109)

OR

Over the Counter Use _____

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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